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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,086	10/30/2003	Ronald H.P. Brus	2578-6158US	9184

24247 7590 02/23/2005

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,086	BRUS ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *8,9,11 and 17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10, and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-30-03*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2-14-05* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (methods of determining if a compound influences a phase of a virus' life cycle), and to embodiments of the invention wherein 1) the virus is a herpes virus, ii) embodiments wherein the cell comprises a nucleic acid encoding an adenovirus early protein 1, and iii) embodiments wherein the method involves the examination of the virus's activity, in the reply filed on January 13, 2005 is acknowledged. It is noted that the arguments in traversal of the restriction were presented in the papers filed on November 19, 2004. The traversal is on the ground(s) that the inventions of Groups I and II are not independent or distinct, and that Groups I-II all share the same classification.

It is noted that the Applicant did not elect a species as required on pages 4-5 of the Restriction Requirement. However, the Applicant's election of the species wherein the herpesvirus is a herpes simplex virus by phone on February 14, 2005 is noted.

The traversal of the restriction between Groups I-III, on the basis that Groups II and III vary from Group I only in "the breadth and scope of the definition of the same disclosed subject matter." While it is not clear what this assertion means, the Applicant provides arguments asserting that the inventions of the different Groups each have the same classification, do not have a separate status in the art, and do not have different fields of search.

With respect to Group II, the claims are drawn to simultaneous methods of determining the effect of two different compounds on two different viruses. Thus, the claimed methods of this Group has a different mode of operation from the methods of Group I, and requires additional

search and examination not required for the inventions of Group I. While the inventions of Group II may be found allowable under the linking claim practice if the method of Group I is found allowable (and the claims of Group II incorporate all of the required limitations), because the methods are distinct for the reasons indicated in the Restriction requirement, and because additional search and examination is required for the these methods not required for those of Group I, the restriction among the inventions is still deemed proper.

The arguments are also not found persuasive with respect to Group III. A search for the inventions of Group III requires a search for different methods than those identified in the other claims. This group is drawn to methods of determining the effects of the absence of a compound on a viral life cycle, while the other inventions are drawn to methods of determining the effects of a compound's presence. Thus, the claims of Group III are drawn not simply to a different breadth, but to a completely different mode of operation and function from the other claimed inventions. A search for one of the other inventions of Groups I-II, will not be coextensive with the search required for, or provide evidence of the patentability of, the methods of Group III. Thus, each of the inventions requires a different field and scope of search. The restriction between Group III and the other Groups is therefore still deemed proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: this claim is drawn to a method for determining the effect of a compound on a life phase of a virus. The other claims, including the elected invention, are drawn to methods of identifying compounds that effect some phase of a

viral life cycle. The method of claim 23 differs from the previously claimed methods in that it is not drawn to a method of identifying an anti-viral compound, but of determining why or how a compound affects the viral life cycle. Thus, the claim performs a different function from that of the other claimed inventions. Additionally, because the claim reads on a method of examining the effect of the compound on the life cycle, rather than merely determining if the is such an effect, the method has a different mode of operation from the other claimed methods.

Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 1-7, 10, and 12-16 are under consideration. Claims 8, 9, 11,17-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 13, 2005.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on October 30, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 101

5. Claims 1-7, 10, and 12-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

These claims are directed to methods of determining "whether a compound influences a phase in the life cycle of a virus." The claims are rejected because, although the Applicant has provided a utility for the claimed methods to the extent that it reads on the identification of compounds with anti-viral activities, there is no utility provided for compounds with no effect or a positive effect (a pro-viral activity). Because there is no utility provided for each of the different types of compounds that may be identified by the present claims, the Applicant has not provided a utility for methods of identifying each of these different types of compounds. It is suggested that the claims be amended to read on the identification of antiviral compounds (compounds that inhibit or interfere with a phase of a viral life cycle), the class of compounds for which the application has provided a utility.

Claims 1-7, 10, and 12-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim has been amended to limit the methods of claim 1 to embodiments wherein the cell "comprises a nucleic acid encoding an adenovirus early protein," rather than specifying that the cell comprises a nucleic acid encoding either the adenovirus early region 1 protein or early region 2 protein. Claim 1, which used to require only the presence of an adenoviral early protein, now requires that the cell comprise the adenoviral E1 protein. Because claim 1 already requires the presence of a specific adenoviral early protein, it is not clear how claim 7 is further limiting of the claim. It is not clear if claim 7 is redundant to claim 1 as amended, or if the claim requires the presence of a nucleic acid encoding an additional adenoviral early protein to the nucleic acid encoding E1 protein required by claim 1. Clarification is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-7, 10, 12, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Burk et al. (WO 91/15573- of record in the October 2003 IDS) in view of Hateboer et al. (WO 00/63403- of record in the October 2003 IDS). These claims are drawn to methods of determining whether a compound has influences a phase in a viral life cycle comprising the steps of providing a cell with at least the viral elements required for the indicated

phase (but may include the whole virus), providing the compound to be tested, and determining whether the compound influences the phase of the viral life cycle. The claims also require that the cell comprises a nucleic acid encoding the adenovirus E1 protein.

Burk teaches the making and use of an immortalized human cell for the production of Hepatitis virus, and viral proteins. Pages 3-4. The reference also teaches that the cells may be used in assays for the identification of compounds that inhibit the growth of virus that can infect the cells. Page 4. Thus, the reference teaches the use of such cells for the identification of compounds that can influence a phase in a viral life cycle. The reference also teaches the immortalization of the cells to be used. Further, the reference also teaches that the methods of identifying anti-viral compounds may include infection of the immortalized cells with whole virus, and then screening for a viral activity, such as its growth. Page 27, lines 16-25. However, while the reference teaches that such immortalization may be performed through the incorporation of virus derived genes into the cells, it does not teach or suggest the use of an adenoviral E1 encoding gene.

Hateboer does teach the immortalization of cells through incorporation of a gene encoding the adenoviral E1 protein into the cellular genome, and the use of such cells for the production of viral proteins. Pages 20-21. Because the cells of Hateboer are similar to those of Burk, it would have been obvious to those in the art that the cells of Hateboer could also be used in similar methods to the cells of Burk, including both for the production of viral proteins, and for the identification of compounds that influence the replication or production of such proteins. Thus, the combination of these references renders the claimed inventions obvious.

10. Claims 1-7, 10, 12-14, and16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burk and Hateboer as applied to claims 1-3, 5-7, 12, 13, and 16 above, and further in view of Lin et al. (J Virol Methods 88: 219-25). Claim 14, which was not rejected over Burk and Hateboer above, further requires that the compound to be tested is compound from a library. The teachings of Burk and Hateboer have been described above. While these references suggest the use of E1 immortalized cells for the identification of anti-viral compounds, they do not explicitly teach the identification of compounds from a library. However, Lin teaches a high-throughput method for the identification of anti-herpesvirus compounds. While the reference does not teach the use of a cellular detection method, the reference does teach the identification of potential anti-viral compounds from a library, and subsequent testing of the identified compound in a cell-based assay. Page 225. It would therefore have been obvious to those in the art to further test the compounds identified by the high-throughput assay disclosed in the reference in the assay suggested by Burk and Hateboer. Thus, the combined teachings of these references teach the methods of identifying anti-viral compounds (i.e. compounds that influence a phase of a viral life cycle) using the cells of Hateboer, wherein the compounds are from a compound library. The combined teachings of these references therefore render the claimed invention obvious.

11. Claims 1-7, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burk and Hateboer as applied to claims 1-3, 5-7, 12, 13, and 16 above, and further in view of Halliday et al. (WO 99/51776- of record in the October 2003 IDS). These claims are directed to high-throughput methods of identifying anti-viral compounds using the method of claim 1. While the teachings of Burk and Hateboer teach the method of claim 1, the references do no

teach that the method would be suitable for high-throughput screening. However, the Halliday et al. reference teaches a high-throughput method of identifying anti-viral compounds comprising a substantially similar method to that suggested by Burk and Hateboer. See e.g., Halliday, claim 1, and pages 5-6. Because the reference teaches that such high-throughput methods are useful for the screening of large numbers of compounds (page 1), it would have been obvious to those in the art to adapt the methods of Burk and Hateboer such that they could be used as high-throughput methods as suggested by Halliday. The combination of these references therefore renders the claimed inventions obvious.

Conclusion

12. No claims are allowed.

13. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Homa et al., U.S. 2002/0076789. This reference teaches a method for the identification of anti-herpes viral compounds. See e.g., page 5, paragraph [0097]. However, the reference does not teach the use of an E1 immortalized cell line, or the use of a high throughput method.

Each of the following references is considered relevant in that they provide teachings relating to the screening for anti-herpes simplex virus activity. Spector et al., J Virol 72: 6979-87; and Cotarelo et al., J Antimicrob Chemother, 44: 705-08. However, the references do not teach the use of the adenoviral E1 transformed cells as taught by Hateboer. The references are therefore considered redundant to the teachings of Burke with respect to the rejected claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 2/18/05

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